DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 13 2002

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Cindy K. Angerhofer, Ph.D.
Director of Research
Tom's of Maine
Lafayette Center
P.O. Box 710
Kennebunk, Maine 04043-0710

Dear Dr. Angerhofer:

This is in response to your letters to the Food and Drug Administration (FDA) dated August 27, 2001 and November 14, 2001. Your letters responded to our letter of August 3, 2001 and our verbal request for additional information regarding statements used with the products Natural Bronchial Syrup for Children and Natural Bronchial Syrup for Adults that we cited as a basis for concluding that these products appeared to be drugs under the Federal Food, Drug, and Cosmetic Act (the Act).

In your letter you stated that you intend to revise some claims that we identified in our letter as not being claims that may be made in the labeling of a dietary supplement pursuant to 21 U.S.C. 343(r)(6). You proposed to replace the claims that we cited in our earlier letter with the claims "supports healthy bronchial passages" and "supports a healthy respiratory system." Based on the information in your letter, these claims appear to be claims that may be made in the labeling of a dietary supplement pursuant to 21 U.S.C. 343(r)(6) and we have no further comment on these statements.

In our letter, we asserted that the products also did not appear to meet the statutory definition of a dietary supplement in 21 U.S.C. 321(ff) because they were not "intended for ingestion." We based that assertion on the fact that the products were, in part, intended to "soothe a dry throat" and that this representation evidenced that the products appeared to achieve their intended effect prior to ingestion. In your letter, you stated that you did not believe that this statement was either a disease claim or a structure/function claim. Instead, you stated that it is merely a claim that is "a reference to a property of the syrup vehicle" that may be made for the product. You cited statements made by FDA in several over-the-counter (OTC) Tentative Final Monographs regarding the use of the term "soothe" in certain OTC cough/cold remedies and asserted that these statements by FDA established that statements such as "soothe" could be made to describe a characteristic of the product but that the use of the term was not relevant to establishing the intended use of the product.

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We disagree with your analysis. Dietary supplements are not OTC drugs, and the regulatory requirements that apply to OTC drugs and dietary supplements are different. 21 U.S.C. 343(r)(6) provides that a statement may be made for a dietary supplement if the statement, among other things, "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans," "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function," or "describes general well-being from consumption of a nutrient or dietary ingredient." It is indisputable that your product describes an effect of the product on a structure or function of the body. Specifically, you state that the product is "to soothe a dry throat." This is a claim that is squarely within the scope of 21 U.S.C. 343(r)(6). The throat is a structure of the body and the claim describes the effect of the dietary supplement on the throat. Moreover, it describes an effect of the product that is achieved prior to ingestion. And, therefore, your product does not meet all of the elements of the statutory definition of a dietary supplement when labeled for use to soothe a drug throat and it is, therefore, not a dietary supplement for throat use.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New England District Office, Compliance Branch, HFR-NE240

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John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Washington, D.C. 20204

August 27, 2001

Dear Mr. Foret,

We have received your Courtesy Letter noting objections to the statements of nutritional support filed for Tom's of Maine's Natural Bronchial Syrups. I can assure you that we are committed to labeling and marketing these products as dietary supplements, and not as drugs. While we don't agree that the claimed effects on bronchial passages cause the products to be drugs (by suggesting that they are intended to prevent, treat, or mitigate upper respiratory disease), in the spirit of our longstanding cooperation with FDA we are proposing to replace those statements with the following:

"Supports healthy bronchial passages"

"Supports a healthy respiratory system."

(Both of these effects are accomplished by the ingestion of the products.) We plan to implement these changes at the time of our next print run for the affected packaging and collateral materials (currently anticipated for December, 2001).

Your letter also addresses the claim "sooth[es] dry throat," apparently assuming that it is a disease claim or a structure function claim. We would like to suggest a different way to think about this issue. In the past, FDA has repeatedly said (in the OTC review) that "soothing" and similar terms can be used to describe the effect of vehicles in syrups, gels, etc. without causing the

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product to be a drug. Also, the term "dry throat" is not usually understood by consumers or medical professionals as a disease condition; it, like dry skin, can result from any number of environmental conditions such as low humidity/dry air, smokiness, or pollution.

For these reasons, we don't think the "sooth[es] dry throat" claim is either a drug claim or a dietary supplement claim; it is merely a reference to a property of the syrup vehicle. In retrospect, we should not have included this claim in our notification.

Sincerely,

Cindy K. Angerhofer

Cindy K. Angerhofer, Ph.D.
Director of Research

Cc: T. Chappell, L. Batcha, T. O'Brien,
S. Armentrout, K. Taggersell, S. Engesser

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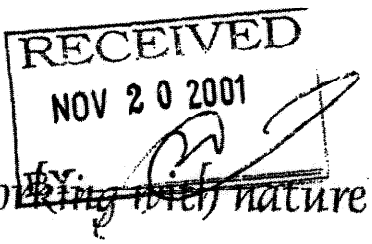

working with nature to make a difference

November 14, 2001

Mr. Bradford W. Williams
Office of Nutritional Products, Labeling,
and Dietary Supplements
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Dear Mr. Williams:

This letter responds to your request for additional information on how FDA has treated the word "soothing" in the OTC Review. In my letter of August 27, 2001, I said that FDA has repeatedly said in the OTC review that "soothing" can be used to describe the effect of a vehicle without creating a drug claim. This letter provides some references to support that statement.

From our research, it looks as if the first place FDA addressed the use of the word "soothing" was in the tentative final monograph for OTC oral health care drug products. As part of a response to a question on whether sugar could be an active demulcent ingredient; FDA noted that

> . . . terms such as "soothing" may be used to describe the action of a sugar-based syrup or lozenge. The term is not a demulcent claim but describes certain physical and chemical attributes of a drug product and is distinctly separate from labeling indications. Terms describing product characteristics (e.g., color, odor, flavor, and feel) appear in the labeling for the consumers' information. Because such claims are not directly related to the safe and effective use of OTC oral health care drug products, the agency considers these claims to be outside the scope of the monograph.

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53 Fed. Reg. 2436, 2450 (January 27, 1988) (Attached at A). In later monographs, FDA made the same point. See, e.g., Oral Discomfort Tentative Final Monograph, 56 Fed. Reg. 48302, 48317 (September 24, 1991) (Attached at B). Perhaps most relevant to the discussion of Tom's Bronchial Syrup is the Final Monograph for Expectorant Drug Products, 54 Fed. Reg. 8494, 8508 (February 28, 1989), where FDA applied the principle to throat soothing. There, the agency said:

> . . . the agency recognizes that many cough-cold drug products are formulated with inactive ingredients such as sugar-based syrups and other mucilaginous substances that can provide a soothing effect on the mucosa of the throat. As discussed in the tentative final monograph for OTC oral health care drug products, . . . terms such as "soothing" may be used to describe the action of a sugar-based syrup or lozenge. Use of the term is not considered making a demulcent claim because the term describes certain physical and chemical attributes of a drug product and is distinctly separate from labeling indications.

(Attached at C).[1]

I know that, in the past, CFSAN has commented on certain "soothing" claims on dietary supplement products. As far as I know, however, when CFSAN objects, it is because the product does not achieve its structure and function effects through ingestion, which is

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1. In other monographs, FDA has applied a slightly different but consistent logic - that soothing claims are cosmetic rather than drug claims. In its notice withdrawing the Vaginal Products Advanced Notice of Proposed Rulemaking, 53 Fed. Reg. 5226, 5231 (February 3, 1994), in response to a comment that certain claims are cosmetic claims, FDA said:

> The agency agrees that cosmetic claims should not be included in OTC drug rulemakings. Therefore, the cosmetic claims "cleansing," "soothing," refreshing," and "deodorizing" will not be included in drug monographs.

(Attached at D). It also noted soothing as a cosmetic effect in the Tentative Final Monograph for Skin Protectant Drugs, 48 Fed. Reg. 6820, 6828 (February 15, 1983) (Attached at E), and in an amendment to that tentative final monograph (for astringents), 54 Fed. Reg. 13490, 13494 (April 3, 1989) (Attached at F) and in the Anorectal Tentative Final Monograph. 53 Fed. Reg. 30756, 30779 (August 15, 1988) (Attached at G).

required for dietary supplement status. In the case of Tom's Bronchial Syrup, the dietary supplement ingredients intended to achieve the product's structure and function effects are, in fact, ingested. The product's soothing effect is an attribute of the vehicle, and, consistent with the logic of the OTC monographs, the soothing claim is not a disease or structure and function claim.

Please let me know if I can provide any additional information.

Sincerely,

Cindy K. Angerhofer

Cindy K. Angerhofer
Director of Research